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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/073,596 05/06/98 STEINMAN R 20164000USS

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HM12/0103

KM  
EXAMINER

VANDER VEGT, F

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<i><b>Office Action Summary</b></i>	Application No. 09/073,596	Applicant(s) <b>Steinman et al</b>
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

Responsive to communication(s) filed on Oct 3, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 82-101 ~~is/are~~ pending in the application.

Of the above, claim(s) 86-88, 90-93, 98, and 100 ~~is/are~~ withdrawn from consideration.

Claim(s) \_\_\_\_\_ ~~is/are~~ allowed.

Claim(s) 82-85, 89, 94-97, 99, and 101 ~~is/are~~ rejected.

Claim(s) \_\_\_\_\_ ~~is/are~~ objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been  received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### **DETAILED ACTION**

This application is a divisional of application S.N. 08/458,230, which is a divisional of application S.N. 08/040,677, which is a continuation-in-part of application S.N. 07/981,357, which is a continuation-in-part of application S.N. 07/861,612. Applicant should amend the priority information on page 1 of the specification to update the status of each of the priority applications, including adding the relationship of the instant application to the 08/040,677 application on the declaration, and to combine the data inserted before line 5 and the data at lines 5 12-15 into a single priority statement.

New claim 101 has been added.

10 Claims 82-101 are currently pending in this application.

#### ***Election/Restriction***

1. Claims 86-88, 90-93, 98 and 100 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable 15 generic or linking claim. Election was made **without** traverse in Paper No. 6.

2. In view of the amendment filed October 3, 2000, only the following rejections are maintained.

20 ***Claim Rejections - 35 U.S.C. § 112***

3. Claim 99 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 99 is maintained to be ambiguous and unclear in the recitation of milligrams of 25 antigen per dose, as it is unclear how many pulsed cells comprise a dose. There is no relation in the claims of antigen amount to cell quantity or density of antigen density upon the surface of the cells in the composition.

Applicant's arguments filed October 3, 2000 have been fully considered but they are not persuasive.

Applicant positions that the claim is not unclear because one of skill in the art would understand the metes and bounds of the claim. This is not persuasive because the claim in reciting 5 a finite amount of antigen without giving any indication what a 'dose' of cells comprises gives no indication regarding the ability of the 'dose' of dendritic cells to present a sufficient level of processed peptide on their surface for presentation to reactive T cells.

**4. The following new grounds of rejection are necessitated by Applicant's amendment.**

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*Claim Objections*

5. Claims 83-85, 89, 94-97 and 99 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon more than one claim simultaneously. See MPEP § 608.01(n).

15 Claim 83 is co-dependent upon both claims 82 and 101 at the same time. In the interest of more efficient prosecution, claim 83 was considered here as bodily incorporating the limitations of claim 82 and being singly dependent upon 101.

Claims 84 and 85 are further objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See 20 MPEP § 608.01(n).

Claim 84 is improperly multiply dependent on both claims 82 and 83 and claim 83 is itself a multiple dependent claim.

*Claim Rejections - 35 USC § 112*

25 6. Claims 83-85, 89, 94, 95 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 83-85, 89, 94-95 and 101 are ambiguous and unclear in that they are drawn to “processed antigen presenting dendritic cell precursors” which present antigen in base claim 101. This is unclear because once dendritic cells express antigenic fragments on their surface, they are no longer precursors, rather they become mature antigen presenting cells. Accordingly, because 5 the object of the claims is still the dendritic cell precursors, the recitations of presenting processed antigen do not provide meaningful limitation to the claimed invention.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the 10 basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 82-85, 89, 94-97 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated 15 by Markowicz et al (J. Clin. Invest. 85:955-961 on form PTO-1449, newly cited).

The Markowicz et al reference teaches the isolation and maturation of dendritic cells from human peripheral blood by the in vitro addition of GM-CSF (Abstract in particular). Markowicz et al teaches that GM-CSF not only increases the survival of dendritic cells in vitro, but also stimulates “DC differentiation to mobile, reversibly adherent cells with long-branched projections. 20 Accordingly, Markowicz et al teaches the maturation of the large irregularly shaped precursors seen in peripheral blood into the differentiated antigen-presenting cells seen in lymphoid organs when cultured in vitro with GM-CSF. The prior art teaching anticipates the claimed invention.

***Conclusion***

25 8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 17, 2000 prompted the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

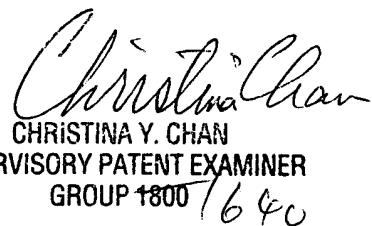
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calendar) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.



F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
January 2, 2001



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